

specified concentrations and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 12 to 17.6 percent in a collodion-like vehicle.

§ 358.550 Labeling of corn and callus remover drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "corn and callus remover."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section and may contain the additional phrase listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the removal of corns and calluses."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain the following statement: "Relieves pain by removing corns and calluses."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 358.510.* (i) "For external use only."

(ii) "Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation."

(iii) "If discomfort persists, see your doctor or podiatrist."

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g., "extremely

flammable," "flammable," "combustible," consistent with 16 CFR 1500.3(b)(10).

(ii) "Keep away from fire or flame."

(3) *For any product formulated in a volatile vehicle.* "Cap bottle tightly and store at room temperature away from heat."

(4) *For any product formulated in a collodion-like vehicle.* (i) "If product gets into the eye, flush with water for 15 minutes."

(ii) "Avoid inhaling vapors."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing salicylic acid identified in § 358.510(a).* "Wash affected area and dry thoroughly." (If appropriate: "Cut plaster to fit corn/callus.") "Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed)." (Optional: "May soak corn/callus in warm water for 5 minutes to assist in removal.")

(2) *For products containing salicylic acid identified in § 358.510(b).* "Wash affected area and dry thoroughly. Apply" (select one of the following, as appropriate: "one drop" or "small amount") "at a time with" (select one of the following, as appropriate: "applicator" or "brush") "to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed)." (Optional: "May soak corn/callus in warm water for 5 minutes to assist in removal.")

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

[55 FR 33261, Aug. 14, 1990, as amended at 57 FR 44494, Sept. 28, 1992]

Subpart G—Pediculicide Drug Products

SOURCE: 58 FR 65455, Dec. 14, 1993, unless otherwise noted.

§ 358.601 Scope.

(a) An over-the-counter pediculicide drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 358.603 Definition.

As used in this subpart:

Pediculicide drug product. A drug product for the treatment of head, pubic (crab), and body lice.

§ 358.610 Pediculicide active ingredients.

The active ingredients of the product consist of the combination of pyrethrum extract (providing a concentration of pyrethrins of 0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

[63 FR 43303, Aug. 13, 1998]

§ 358.650 Labeling of pediculicide drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a “pediculicide (lice treatment)” or “lice treatment.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the following: “For the treatment of head, pubic (crab), and body lice.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “Use with caution on persons allergic to ragweed.”

(2) “For external use only. Do not use near the eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina, as irritation may occur. Keep out of eyes when rinsing hair. Adults and children: Close eyes tightly and do not open eyes until product is rinsed out. Also, protect children’s eyes with washcloth, towel or other suitable material, or by a similar method. If product gets into the eyes, immediately flush with water.”

(3) “If skin irritation or infection is present or develops, discontinue use and consult a doctor. Consult a doctor if infestation of eyebrows or eyelashes occurs.”

(4) The word “physician” may be substituted for the word “doctor” in any of the warning statements in this paragraph.

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) *For all products.* “Important: Read warnings before using.” [statement in boldface type]

(2) *For nonshampoo products.* “Apply to affected area until all the hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Wash area thoroughly with warm water and soap or shampoo. A fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice.”

(3) *For products formulated for use as a shampoo.* “Apply to affected area until all the hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Add sufficient warm water to form a lather and shampoo as usual. Rinse thoroughly. A fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice.”